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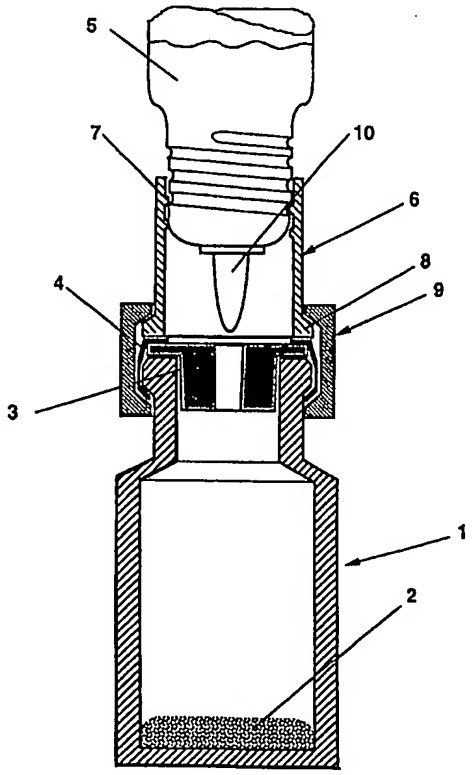
(54) Title: DUAL VIAL CONNECTING SYSTEM

(57) Abstract

For temporary connection of two containers (1, 5) such as vials, bottles, etc., with guaranteed tightness thanks to a two piece tubular connecting device (6, 9) having either a perforable plastic membrane (12) located between its upper piece (6) and the lower piece (9) including a first sealing ring (16) fixed around a plastic skirt (15) located under the bottom of the upper piece, and a second sealing ring (17) fixed inside the upper piece, or alternatively, a rubber stopper (3) in the vial neck covered by the two piece tubular connecting device, the whole assuring complete tightness of the system when stored and when used for reconstitution of the products.



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DUAL VIAL CONNECTING SYSTEM

The present invention concerns a dual vial connecting system for temporary connection of two containers, namely a glass vial and a plastic bottle, for the purpose of reconstituting a lyophilized or powder product contained in the glass vial or plastic container with a corresponding solvent product contained in the plastic bottle, the connecting system having tubular closing and connecting means with a lower portion for connection to the neck of the glass vial, an upper portion having an internal thread for screwing connection with of the plastic bottle and sealing means being perforable by the orifice reducer of the plastic bottle when screwed into the upper portion of the closing and connecting means.

For reasons of stability, freshness, marketing aspects etc. the two products (respective contents of the two containers) are kept and stored in separate containers prior to their immediate use. During storage the two containers are hermetically closed.

In a commonly used prior art system the closing and connecting means is constituted by a cylindrical ring which is combined with a rubber stopper for tightness and connection between the glass vial and the plastic bottle. For connecting two containers of this type it is known to screw the plastic bottle containing the solvent into the upper internal threaded portion of the closing and connecting ring snapped on the glass vial containing the product. When screwing in the solvent bottle, the orifice reducer perforates a membrane. The plastic bottle is compressed in order to transfer the solvent into the glass vial. A solution is formed when shaking the assembly. By inverting the assembly, the solution is caused to return into the plastic bottle when squeezed.

Reference is made to co-pending international patent application N° PCT/EP 97/04660 in which a dual vial connecting system is described which operates without a rubber stopper and is characterized by sealing rings to ensure tightness of closure and connection.

The aim of the present invention is a dual container connecting system, which may or may not have a rubber stopper but ensures a tight closure of the glass vial containing the lyophilized product as well as a tight connection between the glass vial and the solvent bottle and at the same time is more flexible in the choice of resins, colorants and applications.

According to the invention this is achieved by the upper portion and the lower portion of the closing and connecting means being two separate pieces, the upper piece having an essentially tubular shape fitting onto the upper portion of the rubber stopper and/or the glass vial neck and having a threaded interior surface for accomodating the threaded neck portion and the orifice reducer of the plastic bottle and a flanged lower rim resting on the opening of the glass vial, the lower piece being constituted by a sleeve fitting over the flange of the upper piece and the glass vial neck to hold the upper piece on top of the glass vial.

According to another preferred embodiment of the invention the glass vial is closed in a conventional manner by a rubber stopper held by an aluminum ring. In this embodiment the sleeve fits over both the tubular upper piece as well as the rubber stopper and the aluminum ring.

The various measures known in the prior art or contained in the above-mentioned co-pending patent application for improving tightness may of course be combined with the present invention.

In the following preferred embodiments of the invention are described with regard to the accompanying drawings, wherein :

Fig. 1 shows a schematic representation of one preferred embodiment of the dual vial connecting system according to the invention and

Fig. 2 shows another preferred embodiment of the dual vial connecting system according to the invention

A glass vial 1 contains a solid product such as a lyophilisate 2. The glass vial shown in Fig.1 is closed by a rubber stopper 3 which is held in place by an aluminum cramping ring 4. In order to obtain a ready to use solution, this substance has to be mixed or redissolved with a solvent stored separately in a second container 5 made of a flexible material such as plastic. For the mixing and reconstitution process, the two containers have to be connected in such a way that the solvent may be transferred into the glass vial containing the lyophilisate and where the mixing and reconstitution takes place. After shaking the solution contained in the glass vial 1, the system is inverted, having now the glass vial on top so that the solution may be retransferred into the plastic bottle by squeezing the plastic bottle 5. During this entire process, no liquid must be lost and no leakage must occur.

An upper piece 6 of a plastic closing and connecting means has a tubular shape and is provided with a threaded inner surface 7 and a flange 8 at its lower end. The flange 8 has a conical upper surface. Upper piece 6 is placed on top of the rubber stopper 3 and ring 4 and is held in place by a sleeve 9 which due to conical internal surfaces exerts pressure onto the flange 8 of upper piece 6. Thus, secure and tight connection between the upper piece 6 and the vial 1 is ensured.

When the solvent plastic bottle 5 is screwed into the thread of the upper piece 6 its orifice reducer 10 perforates a membrane on top of the rubber stopper 3 and assures tightness by being in contact with the wall of the center hole of the stopper 3. The two containers are now connected and the

transfer of the solvent contained in the plastic bottle 5 into the glass vial 1 containing the lyophilisate 2 may be effected by squeezing the plastic bottle 5. After re-constitution, the solution may be sucked back into the plastic bottle 5 by inverting the assembly. The whole procedure can be made without any spilling or leakage.

The embodiment shown in Fig. 2 is very similar to one embodiment of co-pending international patent application N° PCT/EP 97 04660 which is hereby incorporated by reference. The following description mainly emphasizes the distinctions rather than repeating the features already described in the reference.

In the embodiment of Fig. 2 the glass vial 1 is not closed by a rubber stopper but is directly closed by the upper piece 6 of a closure and connecting means. The upper piece 6 has an integral membrane 12 and sealing rings 16, 17. Similar to the embodiment of Fig. 1 the upper piece 6 has a threaded internal surface 14 and a flange 13 at its lower rim.

Tightness between the upper piece 6 and the vial neck is ensured by two cooperating features: A skirt 15 extends downwardly from the membrane 12 and has an outer diameter fitting into the inner bottle neck. The skirt 15 is an integral part of the upper piece 6, i.e. it is molded in one piece with the latter. The second means for effecting tightness is the elastomer sealing ring 16 placed around the skirt 15, thus being positioned between the flange 13 and the vial neck. Inside the upper piece 6 is located the sealing ring 17 to guarantee complete sealing.

The major advantage of this second embodiment is its special suitability for fully automatical lyophilisation process, as described in detail in the referenced co-pending patent specification.

In addition to the two embodiments described above various combinations of prior art systems may easily be combined with

the essential features of the present invention without exceeding the scope of the invention.

CLAIMS

1. A connecting system for temporary connection of two containers, namely a glass vial and a plastic bottle, for the purpose of reconstituting a product contained in the glass vial with a corresponding solvent product contained in the plastic bottle, the connecting system having tubular closing and connecting means with a lower portion having inwardly directed projections for snapping connection to the neck of the glass vial, an upper portion having an internal thread for screwing connection with of the plastic bottle and an integrated membrane being perforable by the orifice reducer of the plastic bottle when screwed into the upper portion of the closing and connecting means, characterised by the closing and connecting means being constituted by an essentially tubular connection and closure piece fitting onto the glass vial neck and having an upwardly extending annular collar for accommodating the threaded neck portion and the orifice reducer of the plastic bottle and a lower flanged portion for resting on the opening of the glass vial, and a separate sleeve fitting over the flanged portion of the the glass vial neck to hold the connection and closure piece on top of the glass vial.

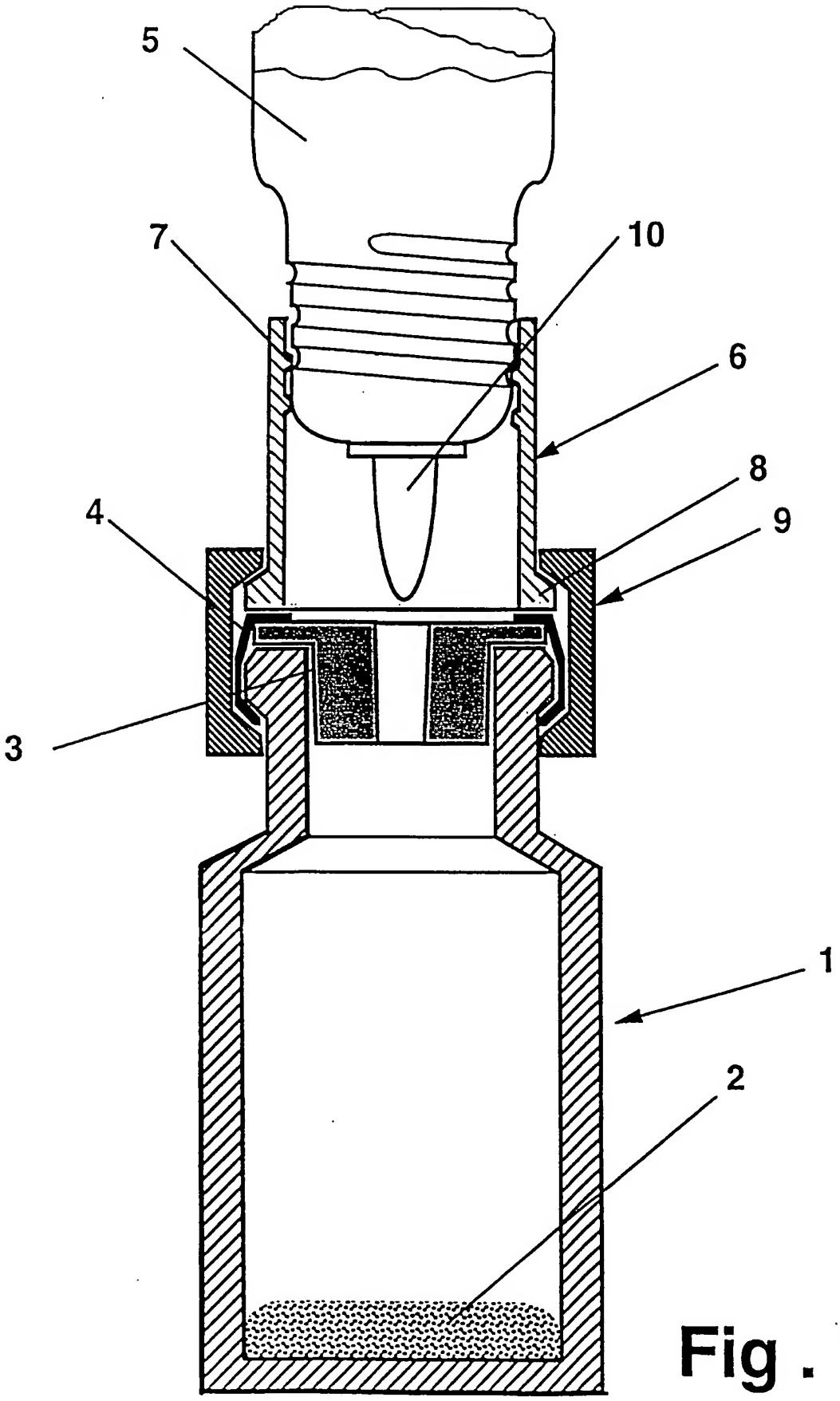

Fig . 1

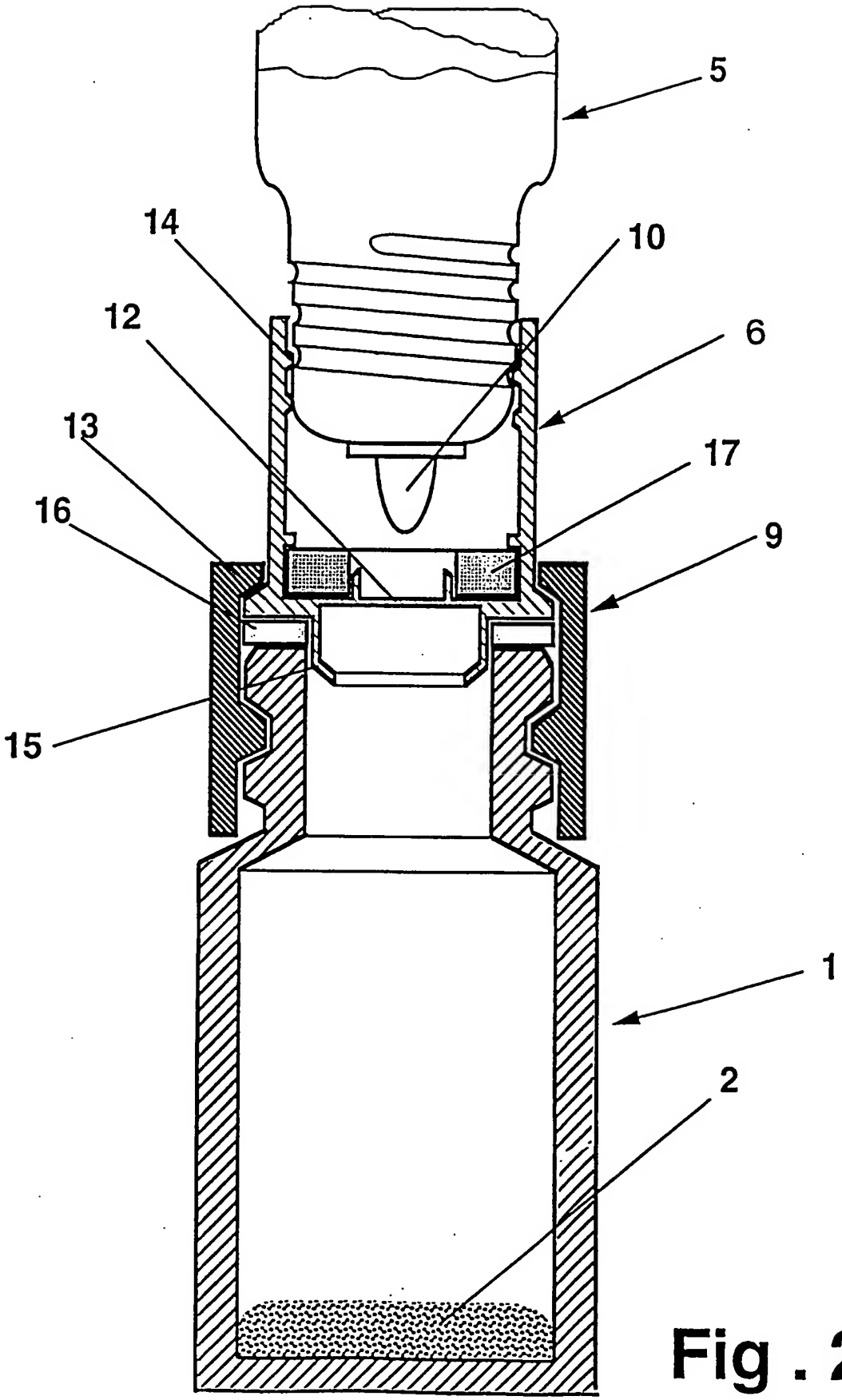

Fig . 2

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/EP 98/04290

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D81/32 A61J1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 188 565 A (SEMCO) 18 January 1974 see the whole document	1
A	EP 0 793 954 A (MANNI & AUGIER) 10 September 1997 see abstract; figures	1
A	FR 2 682 088 A (SEMCO) 9 April 1993 see abstract; figures	1
A	EP 0 283 629 A (SEMCO) 28 September 1988 see abstract; figures	1
A	FR 2 427 960 A (DEHAIS) 4 January 1980 see figures	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 February 1999	03/03/1999

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No
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